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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/557,011	04/20/2000	Natarajan Ranganathan	KBI-0003	6238

7590 01/29/2002

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EXAMINER	
PATTEN, PATRICIA A	
ART UNIT	PAPER NUMBER
1651	CJ

DATE MAILED: 01/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/557,011	RANGANATHAN ET AL.	
	Examiner	Art Unit	
	Patricia A Patten	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) *5-7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicants pointed out in the Amendment dated 9/4/01 (Paper No. 13) that the Office Action dated 6/4/01 was improperly made final because the Examiner had pointed out in the Final Office Action prior to the filing of the CPA that new limitations to the claims would require a new consideration and search of the claimed subject matter. These arguments were persuasive, and thus the Finality of the Office Action dated 6/4/01 has been withdrawn.

Claims 1-7 are pending in the application. It is noted that Applicants have indicated (as well as the Examiner) that only claims 1-4 are pending in the application. However, the Examiner cannot find where claims 5-7 were cancelled by any amendment. If Applicants believe that claims 5-7 have been canceled, the Applicants are asked to point out the specific amendment where these cancellations took place.

Claims 5-7 were withdrawn from consideration in paper No. 2 as being drawn to a non-elected invention.

Claims 1-4 were presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4 state 'gut clearance rate.' The term 'gut' is indefinite in that it is not known exactly what 'gut' the claim is referring to. Is this a rat gut, human gut, murine gut? It is thought that the rate of clearance upon use of particular amounts of sorbents would differ with respect to the size of the gut in question. Thus, the claims are deemed to be confusing and indefinite because the meets and bounds of the term 'gut' are not clearly delineated.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 are newly rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation

needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

As the state of the art stands, kidney disease is one of the highest ranking diseases in the United States. Applicants point out in the Instant specification that disease treatments are scarce, wherein the most prevalent treatment for kidney disease is dialysis, thus, making successful treatments for kidney disease patients rare.

In the instant case, Applicants are claiming a mixture of sorbents which posses a gut clearance rate for urea of at least 5.6 ml/min. However, the Instant specification as filed does not specifically teach a mixture which would posses this

limitation. Further, there are no working examples which indicate a mixture which possess a gut clearance rate of at least 5.6 ml/min.

Applicants have pointed out on page 11 of the Specification that the "gut clearance rate should be 5.6 ml/min. Sorbent capacity lower than this, such as 5.4 grams of urea/day will at best delay dialysis by months...". Applicants further point out the source of the particular sorbents such as oxystarch and Locust bean gum (pp. 11-12) and compare sorbents and shell systems to particle size (p. 13). Applicants show different mixtures of sorbents in Table 2, and convey that they test these mixtures against different concentrations of E.coli (p.15) *in vitro* (p. 4-18 and *in-vivo* (pp. 18-19). Applicants specifically state on p.17 (in vitro study) that "...five optimized mixtures of modified sorbent formulations with microencapsulated E.Coli DH5 cells will be selected for studies in the TNO computer controlled Gastro-Intestinal tract model.....". However, upon reading the section on TNO Gastro-Intestinal Model, it is not taught what mixture of the sorbents was used in order to evaluate the rates of adsorption; nor was any verifiable data presented.

Moving on to the *in vivo* studies, again, it is not found where a particular mixture of sorbents was used. Applicants state "One group is treated with oral feeding of sorbents along with Kayexylate to control potassium.....If sorbents are effective, some prolongation of life will be observed in the treated groups as compared to the nontreated group" (p.18, second full paragraph). However, there is no indication what sorbents were used in the study.

The first paragraph of 35 U.S.C. § 112 requires that the breadth of claims must be based upon the predictability of the claimed subject matter and not on some standard of trial and error. To argue that one can make material embodiments of the invention and then test for those that work in the manner disclosed or that the instant claims only encompass the working embodiments is judicially unsound. Unless one has a **reasonable expectation** that any one material embodiment of the claimed invention would be more likely than not to function in the manner disclosed or the instant specification provides sufficient guidance to permit one to identify those embodiments which are **more likely to work that not** without actually making and testing them then the instant application does not support the breadth of the claims.

The Instant specification leads one of skill in the art to question the nature of the claimed invention: Which sorbents were successful? Which sorbents were actually found to posses a gut clearance rate of at least 5.6 ml/min? In order to answer such questions, the skilled artisan would need to perform undue experimentation encompassing tedious trial and error protocols in order to ascertain the effectiveness of each of the mixtures of sorbents as presented in Table 2. Thus, one of skill in the art could not practice the invention as instantly claimed taking into consideration the lack of guidance set forth in the Instant specification.

The inadequate disclosure coupled with a lack of representative examples and the art recognized unpredictability with respect to the effects of bioactivity of making even subtle changes to the chemical structure of the underlying compounds, thus

preclude the making and use of compounds within the scope of the presently claimed invention by the skilled artisan without undue experimentation.

In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

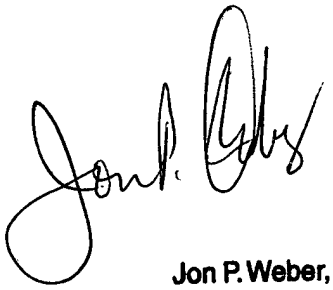
"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Jon P. Weber, Ph.D.
Primary Examiner